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Prospective, multi-center evaluation of a silicon carbide coated cobalt chromium bare metal stent for percutaneous coronary interventions: Two-year results of the ENERGY Registry☆

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ABSTRACT

Background: Novel bare metal stents with improved stent design may become a viable alternative to drug-eluting stents in certain patient groups, particularly, when long-term dual antiplatelet therapy should be avoided.
Purpose: The ENERGY registry aimed to assess the safety and benefits of a cobalt–chromium thin strut bare metal stent with a passive coating in a large series of patients under real-world conditions.
Methods and materials: This prospective registry recruited 1016 patients with 1074 lesions in 48 centers from April to November 2010. The primary endpoint was the rate of major adverse cardiac events (MACEs), a composite of cardiac death, myocardial infarction and clinically driven target lesion revascularization.
Results: More than half of the lesions (61.0%) were type A/B1 lesions, mean lesion length was 14.5 ± 6.5 mm and mean reference vessel diameter 3.2 ± 0.5 mm. MACE rates at 6, 12 and 24 months were 4.9%, 8.1% and 9.4%, target lesion revascularization rates 2.8%, 4.9% and 5.4% and definite stent thrombosis rates 0.5%, 0.6% and 0.6%. Subgroups showed significant differences in baseline and procedural characteristics which did not translate into significantly different clinical outcomes. Specifically, MACE rates at 24 months were 13.5% in diabetics, 8.6% in small stents and 9.6% in acute coronary syndrome patients.
Conclusion: The population of ENERGY reflects real-world conditions with bare metal stents being mainly used in simple lesions. In this setting, percutaneous coronary intervention using a cobalt–chromium thin strut bare metal stent with a passive coating showed very good results up to 24 months. (ClinicalTrials.gov:NCT01056120)
Summary for annotated table of contents: The ENERGY international registry evaluated the safety and benefits of a cobalt–chromium thin strut bare metal stent with passive coating in 1016 patients under real-world conditions until 2 years. Results were encouraging with a low composite rate of cardiac death, myocardial infarction and clinically driven target lesion revascularization, even in the pre-defined high risk groups of diabetes, stents ≤2.75 mm and acute coronary syndrome.

1. Introduction

Bare Metal Stents (BMS) were designed to address the limitations of percutaneous transluminal coronary angioplasty (PTCA) [1], but were still associated with substantial restenosis rates [2–4]. Drug-eluting stents (DES) were introduced to overcome this problem [2,4,5], but

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late and very late stent thrombosis of DES warranted further research [4,6,7]. To address these limitations, several novel technologies have been developed, one of them being BMS with an improved stent design. Cobalt–chromium (CoCr) replaced stainless steel, allowing thinner stent struts with the associated advantages of better flexibility and reduced restenosis rates [5,8,9]. In addition, passive stent coating may further reduce restenosis rates [10,11].

The PRO-Kinetic Energy BMS is a CoCr stent which is covered by a thin layer of amorphous silicon carbide. In animal models, silicon carbide coating has been shown to reduce direct smooth-muscle-cell stimulation [12] and to exhibit lower adhesion and activation of blood platelets and leucocytes [11,13]. It was the aim of the present registry to evaluate the clinical safety and efficacy of this latest generation BMS in a large (>1000 patients) multi-center prospective observational trial to evaluate if the preliminary promising data obtained with a small sample size in the MULTIBENE study [14] can be replicated in daily practice and to assess outcomes in specific pre-defined high-risk groups such as patients with diabetes, small stents, and ACS.

2. Methods

2.1. Study design and population

The ENERGY registry was a prospective, non-randomized, multicenter, observational registry to evaluate the clinical performance of the PRO-Kinetic Energy BMS in a large real-world patient population in standard clinical care. Inclusion criteria were defined according to the instructions for use (eligibility for percutaneous coronary intervention with de novo lesions or re-stenosis after PTCA). Patients with known allergy to anticoagulation/antiplatelet therapy and patients presenting with in-stent restenosis were excluded. Additionally, the use of more than one stent, not being a PRO-Kinetic Energy stent, within the same vessel was discouraged, to allow to distinguish if the target vessel events were related to the PRO-Kinetic stent or not. Clinical follow-ups were scheduled at 6, 12 and 24 months and were performed according to standard of care at the participating sites. The antiplatelet therapy regime was also given according to standard of care at each site. Monitoring included 10% source document verification, randomly chosen. An independent clinical events physician reviewed and adjudicated all suspected major adverse cardiac events, adverse device effects and serious adverse device effects.

2.2. Study device

The PRO-Kinetic Energy BMS (BIOTRONIK AG, Bülach, Switzerland) consists of a balloon-expandable stent pre-mounted on a fast-exchange delivery system. It is composed of CoCr L605 alloy, which is completely covered by a thin layer of amorphous silicon carbide (PROBIO). This layer of passive coating acts as a passive barrier, reducing thrombogenicity and the release of potentially allergic ions [15]. The PRO-Kinetic Energy stent is available in lengths from 9 to 40 mm and diameters from 2.0 to 5.0 mm. Strut thickness is 60 μm for small stents (2.0–3.0 mm diameter), 80 μm for medium stents (3.5–4.0 mm diameter) and 120 μm for large stents (≥4.5 mm diameter).

2.3. Definitions

Lesions were defined according the AHA/ACC classification [16,17]. The primary endpoint of the study was major adverse cardiac events (MACE), a composite of cardiac death, myocardial infarction (MI), and clinically driven target lesion revascularization (TLR), at 6 months. Secondary endpoints were MACE at 12 and 24 months, and target vessel revascularization (TVR), and stent thrombosis at 6, 12 and 24 months as defined by the academic research consortium guidelines [18].

2.4. Statistical analysis

Statistical analysis was performed based on available data for the total subject cohort (intention-to-treat population) and the following subgroups: diabetes (insulin dependent and non-insulin dependent), stent sizes ≤ 2.75 mm in diameter, and ACS [19]. Continuous variables are presented as mean ± standard deviation (SD), and compared using the Student's t-test. Categorical variables are presented as frequencies and percentages, and compared using the Fisher's Exact test or Chi-Square test. 2-year survival was analyzed using the Kaplan–Meier method. A p-value less than 0.05 was considered statistically significant. For MACE, effect size between subgroups was studied using odds ratios. All statistical analyses were carried out using SAS 9.3 (SAS Institute Inc. Cary, NC, USA).

2.5. Role of the funding source

The study was sponsored by BIOTRONIK AG, Bülach, Switzerland. The sponsor was involved in the design of the study, data collection, monitoring, and data analysis and interpretation. The corresponding author had full access to all data in the study and together with the co-authors had final responsibility for the decision to submit for publication.

Ethics committee approval was obtained for all participating institutions and the registry was conducted in accordance with the Declaration of Helsinki, Good Clinical Practice and ISO1455, where applicable. All patients provided written informed consent. This study is registered at ClinicalTrials.gov (NCT01056120).

3. Results

From April 2010 until November 2010, a total of 1016 consecutive patients with 1074 coronary lesions were enrolled at 48 centers in 10 countries in Europe and Israel (Fig. 1). The baseline clinical characteristics are listed in Table 1. The mean age was 66.1 ± 12.5 years, 77.7% (n = 789) were male, 16.5% (n = 168) had diabetes and 7.0% (n = 71) renal failure. Several differences in baseline characteristics between the subgroups were observed. Diabetics were significantly older and had a higher incidence of renal failure, hypertension, hyperlipidemia, unstable angina, previous percutaneous coronary intervention (PCI) and previous cerebrovascular attacks (CVA), but a lower rate of ACS. Patients with small stents were older and had more diabetes and hypertension, but less were male or had a history of smoking. Patients with ACS were younger and had a higher incidence of smokers and a lower rate of diabetes, hypertension, hyperlipidemia, previous coronary artery bypass grafts, MI, PCI and CVA/transient ischemic attacks.

The majority of patients had ACC/AHA lesion classification B1 (n = 435, 40.5%). Lesions involving coronary bifurcations were present in 12.8% (n = 137) (Table 2). The mean reference vessel diameter was 3.2 ± 0.5 mm, mean lesions length 14.5 ± 6.5 mm and mean diameter stenosis 87.0 ± 11.7%. There were significant differences in lesion and procedural characteristics among the subgroups. Most relevant, diabetic patients had significantly more calcification, patients with small stents had more stents per lesion implanted and shorter lesion lengths, and patients with ACS had less calcification, longer lesions and higher mean diameter stenosis.

At 6 months, two thirds (66.8%) of the patients were on dual antiplatelet therapy (DAPT) and 7.8% received anticoagulation therapy, at 12 months, half of the patients (51.9%) received DAPT and 9.2% anticoagulation therapy, and at 24 months 32.3% and 9.1% respectively. At 6, 12 and 24 months, the MACE rates were 4.9%, 8.1% and 9.4%, cardiac death rates 1.7%, 2.9% and 3.4%, MI rates 1.7%, 2.0% and 2.3%, TLR rates 2.8%, 4.9 and 5.4% and definitive stent thrombosis rates 0.5%, 0.6% and 0.6%, respectively. Notably, half of the cardiac deaths were of unknown cause (1.6% at 12 months). All-cause mortality was 4.0% at 12 months and 4.6% at 24 months (Fig. 2).

Fig. 1. Patient status.

Except for cardiac death and all-cause mortality, which were significantly higher in the diabetics group (7.4% vs. 2.7% at 24 months, p = 0.007 and 8.6% vs. 3.9%, p = 0.018, respectively), there was no significant difference in event rates between patients with diabetes, small stents and ACS. Respective MACE rates were 13.5%, 8.6% and 9.6% at 24 months (Fig. 2) with logrank tests of 0.062, 0.658 and 0.750. In the ACS subgroup, there was no significant difference between STEMI and NSTEMI patients (9.8% vs. 10.2%, p = 0.936), or between ACS patients with stents ≤2.75 mm and >2.75 mm (8.1% vs. 9.7%, p = 0.638).

4. Discussion

This prospective, multi-center registry comprising > 1000 all-comer patients undergoing PCI showed that in the era of DES, BMS are mainly used for simple lesions, as also observed in the SCAAR registry [20]. In this setting, the use of a modern-generation thin strut BMS with passive coating results in very good clinical outcomes with low restenosis rates during 2-year follow-up. Even in high-risk patients (diabetics, small vessels, or ACS) clinical outcomes were very favorable with MACE rates of <13.5%.

The overall results were similar to other studies and registries conducted with the PRO-Kinetic stent. At 6 months, clinical driven TLR rate was 3.2% compared to 7.6% in MULTIBENE [14], 5.2% in a single center study [21] and 4.9% in the PRO-Heal registry [11]. MACE rate was 4.9% compared to 8.7% [19] and 5.6% [11]. Further, the revascularization rates of the ENERGY registry compared well to those of registries, randomized studies and meta-analyses of other BMS and DES. At 12 months, the revascularization rate was 4.9% versus 4.6%–17.3% for BMS [2,4,20,22–24] and 2.2%–10.4% for DES [2,4,20,23,25,26]. Definite stent thrombosis occurred in 0.6% of our patients compared to 0.3%–1.2% in BMS as well as DES trials [2,4,20,23–26]. Notably, the antiplatelet regime was left to the discretion of the treating physician and the relatively high rate of DAPT at follow-up might have influenced event rates.

Overall, the low revascularization rates support the hypothesis of a recent analysis of 1.5 million PCI procedures from the National Cardiovascular Data Registry, suggesting that a less frequent use of DES in patients with a low risk of restenosis has the potential for significant cost savings while minimally increasing restenosis rates [27]. Similarly, outcomes of the SCAAR registry suggested that overall low revascularization rates and the small absolute difference between BMS and DES do not support the use of DES in patients with a low or intermediate risk of restenosis [28].

4.1. Subgroup analysis

This registry aimed to assess the risk profile of pre-defined risk groups as treatment strategies amongst several subgroups is still unclear and sometimes stent design can make an eminent difference [29]. As expected, MACE rates at follow-up were numerically higher in the risk groups of diabetics and patients with ACS, yet the differences were not significant and outcomes were still within the range of studies and registries with unselected patient populations.

Table 1
Baseline characteristics.

	Overall	Diabetics		Stents ≤2.75 mm		ACS	
	N = 1016	N = 168	p-value	N = 253	p-value	N = 468	p-value
Age in years, mean ± SD	66.1 ± 12.5	68.7 ± 11.2	0.002	68.2(12.3)	0.004	63.7 ± 13.3	<0.001
Male	789(77.7)	129(76.8)	0.743	182(71.9)	0.022	368(78.6)	0.471
Diabetes	168(16.5)	168(100.0)	–	56(22.1)	0.008	62(13.2)	0.008
IDDM	44(4.3)	44(26.2)	–	17(6.7)	0.024	15(3.2)	0.100
Renal Failure	71(7.0)	20(11.9)	0.007	20(7.9)	0.423	28(6.0)	0.239
History of smoking	636(62.6)	102(60.7)	0.528	144(56.9)	0.041	310(66.2)	0.030
Hypertension	732(72.0)	156(92.9)	<0.001	196(77.5)	0.032	292(62.4)	<0.001
Hyperlipidemia	703(69.2)	140(83.3)	<0.001	173(68.4)	0.788	288(61.5)	<0.001
Indication for PCI							
Stable angina	355(34.9)	63(37.5)	0.460	88(34.8)	0.887	–	–
Unstable angina	140(13.8)	32(19.0)	0.029	42(16.6)	0.152	–	–
ACS	468(46.1)	62(36.9)	0.008	104(41.1)	0.069	468(100.0)	–
Previous CABG	60(5.9)	13(7.7)	0.272	19(7.5)	0.262	13(2.8)	<0.001
Previous MI	196(19.3)	35(20.8)	0.548	52(20.6)	0.541	64(13.7)	<0.001
Previous PCI	234(23.0)	53(31.5)	0.003	67(26.5)	0.119	49(10.5)	<0.001
Previous CVA or TIA	45(4.4)	13(7.7)	0.023	9(3.6)	0.505	13(2.8)	0.017

Data shown as n (%) unless otherwise specified. ACS = acute coronary syndrome; yrs = years; IDDM = Insulin dependent diabetes mellitus; PCI = Peripheral coronary intervention; CABG = Coronary artery bypass graft; MI = myocardial infarction; PCI = percutanous coronary intervention; CVA = cerebrovascular attack; TIA = transient ischemic attack.

Table 2
Baseline lesion and procedural characteristics.

	Overall	Diabetics		Stents ≤2.75 mm		ACS	
	N = 1074	N = 176	p-value	N = 265	p-value	N = 487	p-value
Target vessel			0.147		<0.001		0.300
Right coronary artery	413(38.5)	59(33.5)		71(26.8)		200(41.1)	
Left anterior descending artery	379(35.3)	60(34.1)		105(39.6)		169(34.1)	
Left Circumflex artery	266(24.8)	56(31.8)		82(30.9)		110(22.6)	
Ramus intermedius	10(0.9)	1(0.6)		6(2.3)		5(1.0)	
Unknown	6(0.6)	0(0)		1(0.4)		3(0.6)	
Lesion classification (AHA/ACC)			0.951		0.409		<0.001
Type A	220(20.5)	38(21.6)		56(21.1)		83(17.0)	
Type B1	435(40.5)	72(40.9)		100(37.7)		181 (37.2)	
Type B2	307(28.6)	50(28.4)		74(27.9)		151 (31.0)	
Type C	108(10.1)	16(9.1)		35(13.2)		71 (6.3)	
Unknown	4(0.4)	0(0)		0(0)		1(0.2)	
Bifurcation lesion	137(12.8)	23(13.1)	0.888	44(16.6)	0.061	69(14.2)	0.213
Moderate to excessive calcification	278(25.9)	60(34.1)	0.007	76 (28.7)	0.359	93(19.1)	<0.001
Lesion length, mm ± SD	14.5 ± 6.5	14.0 ± 5.3	0.240	13.7 ± 6.1	0.013	15.7 ± 6.8	<0.001
Mean RVD, mm ± SD	3.2 ± 0.5	3.1 ± 0.5	<0.001	2.6 ± 0.2	<0.001	3.3 ± 0.5	<0.001
Mean diameter stenosis, % ± SD	87 ± 11.7	87.1 ± 10.1	0.862	86.4 ± 12.5	0.355	91.4 ± 10.0	<0.001
Stent diameter, mm ± SD	3.2 ± 0.5	3.1 ± 045	<0.001	2.6 ± 0.2	<0.001	3.2 ± 0.5	0.005
Stent length, mm ± SD	15.8 ± 4.7	15.4 ± 3.8	0.157	15.0 ± 4.2	0.001	16.6 ± 4.9	<0.001
Pre-dilatation	491(45.7)	89(50.6)	0.167	136 (51.3)	0.048	214(44.0)	0.267
Post-dilatation	193(18.0)	25(14.2)	0.152	43 (16.2)	0.305	95(19.1)	0.241
Number of stents per lesion, mean	1.15	1.20	0.817	1.33	0.017	1.22	0.617

Data shown as n (%) unless otherwise specified. ACS = acute coronary syndrome; AHA/ACC = American Heart Association/American College of Cardiology; RVD = reference vessel diameter.

Recently, the RESOLUTE DES received FDA approval for treatment of coronary artery disease in diabetics. The prospectively obtained performance goal was a composite of cardiac death, target-vessel MI and TVR of 14.5% at 12 months in a pre-specified low risk cohort. In a pooled analysis of 878 diabetics enrolled in the global RESOLUTE program this performance goal was met with a 12-month rate of 7.8%. In the overall diabetic group, including complex patients, the composite of cardiac death, target-vessel MI and TLR was 11.7% for insulin-dependent diabetics and 6.1% for non-insulin-dependent [30]. With a 11.41% composite of cardiac death, MI and TLR, and no additional TVR, the event rate of diabetics in ENERGY hence met the performance goal for low-risk diabetics in RESOLUTE. Further, with a TLR rate of 5.9% and a definite stent thrombosis rate of 0.6%, results were similar to a prospective study in diabetics with everolimus and paclitaxel-eluting stents which observed TLR in 4.2%–4.7% and stent thrombosis in 0.8%–1.3% of the cases [29], and to the SCAAR registry which observed revascularization in 5.0% of the patients treated with a BMS and 3.6% of the patients treated with a DES [28].

Similarly, a small stent respective vessel size by itself is known to be associated with higher MACE and revascularization rates [3,28,31]. Clinical studies showed that DES benefit was particularly apparent in small vessels [28,31,32]. Our registry, however, showed remarkably good outcomes in patients with small stents, which were slightly superior to the overall ENERGY population. Furthermore, the revascularization rate of 4.1% at 12 months was lower than published results in other cohorts treated with BMS (6.8%–11.2%) [28,33,34] and within range of those treated with DES (3.2% for the SCAAR registry and 4.4% for the NHLBI dynamic registry at

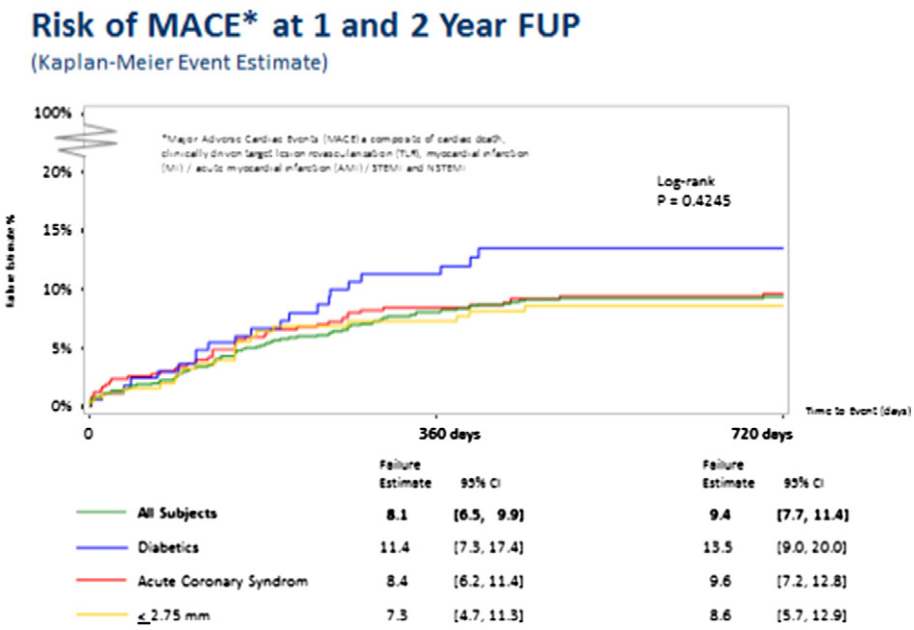


Fig. 2. Cumulative risks for MACE, all-cause mortality, myocardial infarction, clinically driven target lesion revascularization and definite stent thrombosis.

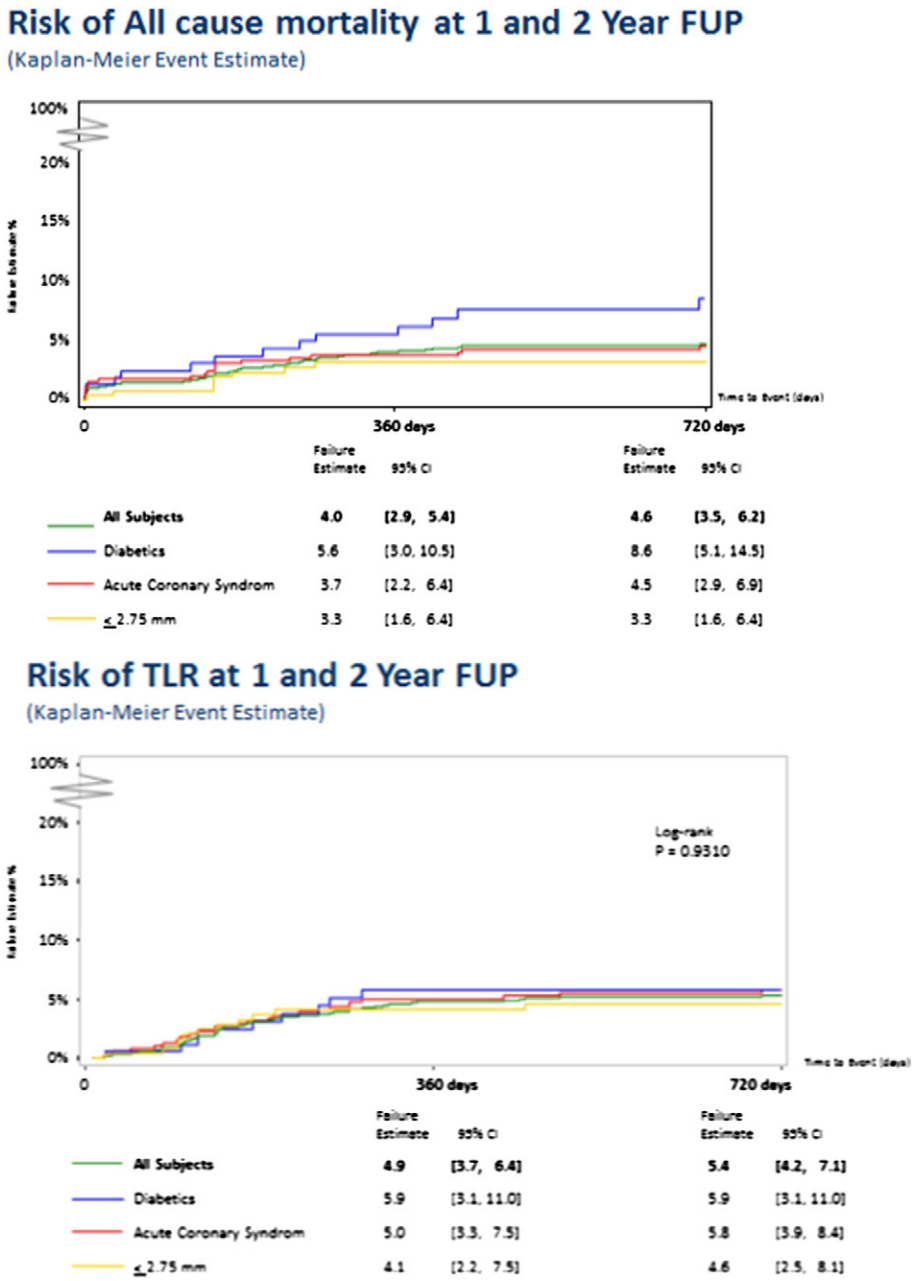


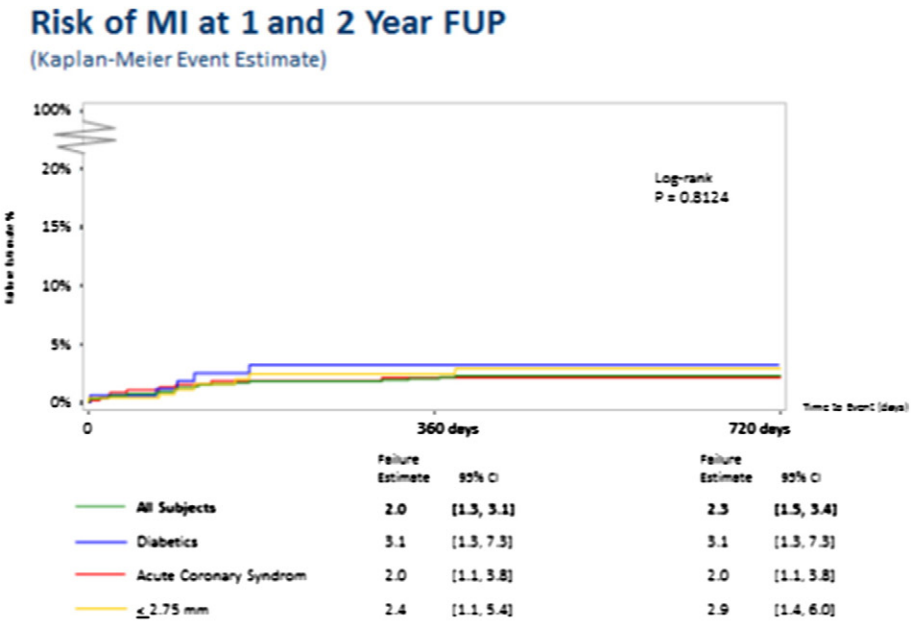
Fig. 2 (*continued*).

12 months and 10.3% at 9 months for the PICOLETTO study) [28,33,35]. The most plausible explanation is that complicated small lesions would likely have been treated with DES or left alone originally and therefore were not included in this registry.

In a recent randomized trial in ACS, a new generation coated BMS achieved a 12-month MACE rate which was non-inferior to an everolimus eluting stent, combined with a slightly higher TLR rate and lower definite stent thrombosis rate (9.6% vs. 9.0%, 6.5% vs. 4.9% and 0.7% vs. 2.2%) [36]. We observed similar results in our registry (8.4%, 5.0% and 0.7%), which are also in alignment with a single center study in ACS treated with a PRO-Kinetic stent (11.1%, 2.6% and 1.8%) [37]. The PROMETHEUS study assessed the safety and efficacy of the PRO-Kinetic stent in patients with acute ST-elevation myocardial infarction (STEMI). At 6 months, the MACE rate was 7.8% including TLR in 6.3% of the patients [38] compared to 6.2% and 3.0% in our registry. Favorable clinical and angiographic outcomes were observed in large (>3.0 mm) arteries, but not in small ones. We, however, observed favorable results in patients with STEMI and small stents ≤2.75 mm too, with a MACE rate of 6.0% and a TLR rate of 2.1%.

4.2. Limitations

The registry was non-randomized and therefore a direct comparison to other coronary stents is not possible. Lesions were mostly not complex, most likely reflecting the daily clinical practice, using BMS only in a selected group of patients and lesions. Thus, a comparison to DES is hampered and biased as the more complex lesions, e.g. small vessels and long lesions, are rather treated with DES than with BMS. Furthermore, there was an unusually long duration of DAPT which is unexplained and which potentially has biased the results. Angiographic assessments are missing as treatment was according to standard of care. Especially under the light of low revascularization rates,



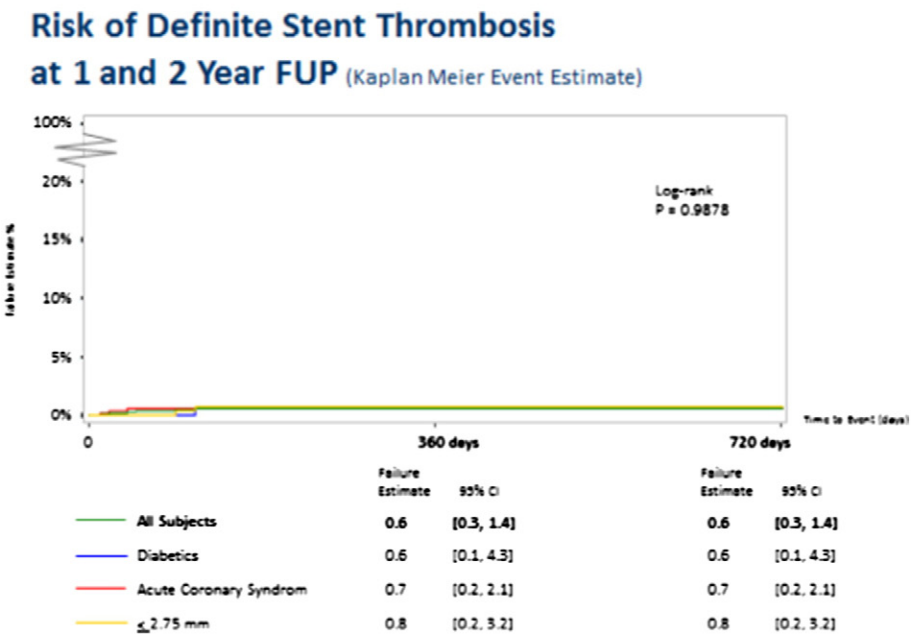


Fig. 2 (*continued*).

parameters like binary restenosis rate and late lumen loss would have been of interest. The average recruitment rate was low, which might be due to a less frequent use of BMS in some centers and due to a short enrollment period in others. However, as in other studies and registries, a non-consecutive enrollment cannot be ruled out. When assessing the 2-year data, it has to be considered that follow-up is only available for 90% of the patients. Furthermore, the small sample size in the subgroups does not allow generalizing the results to populations with diabetes, small stents, and ACS, but can only be regarded as hypothesis generating.

5. Conclusions

The population of ENERGY reflects real-world conditions with bare metal stents being mainly used in simple lesions. In this setting a BMS with very thin struts and passive coating demonstrates very good short and long term results, even in subgroups with small stents and ACS, and acceptable results in diabetics. Utility of such modern BMS platforms in selected groups of patients and lesions is still relevant in the era of DES.

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